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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,825	02/11/2004	Mark E. Cook	960296.00097	5721

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
07/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

Office Action Summary	Application No.	Applicant(s)	
	10/777,825	COOK ET AL.	
	Examiner	Art Unit	
	ANISH GUPTA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3-26-09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-28 and 32-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-28 and 32-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 24-28 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US6213930) in view of Draber et al. and Andya et al. and Freeman (US6746698).

The claims are drawn to a method for heat stabilizing a specific binding activity of a protein by subjecting the protein to a saccharide.

The reference of Cook et al. the use of anti-phospholipids A2 antibodies to enhance growth or improve animal feed (see abstract). The reference states a producer animal is immunized with a peptide or protein, such as PLA.sub.2, against which antibodies are desired so that the producer animal produces an antibody to said peptide or protein. A substance containing the antibody is

obtained from said producer animal. The antibody can be subject to further purification if desired or can be used without further preparation in an animal feed (see col. 3, lines 63-67). Further, An egg preparation, e.g., egg yolks or whole eggs, containing the anti-PLA.sub.2 antibody can be collected and homogenized to form an emulsion. Thereby meeting the imitation of claim 7-12. The resulting emulsion can be dried to form a powder containing the anti-PLA2 antibody. This powder can then be formulated in a manner appropriate to the administration route and then administered to the desired animals using methods known in the art. The preparation is preferably administered orally, most preferably as a supplement to the animal's diet. (see col. 4, lines 14-22). The difference between the prior art and the instant application is that the reference does not teach the use of trehalose and does not teach a processing step at a temperature of at least 70°C.

However, Draber et al. teach the stabilization of antibodies using trehalose. The reference specifically teaches a method where the ascetic fluids or purified mAbs were freeze dreid in the presence of trehalose (see page 38). Trehalose provides effective stabilization during freeze-drying of IgM and such preparations can be stored at elevated temperatures (see page 41). The trehalose freeze dried preparation of IgG and IgM were found to be more stable (see page 41). Trehalose confers unique thermostability to biomolecules including liposome-hemoglobin, air-dried antibodies (see page 41). The reference of Andya et al. teach that anti-IgE monoclonal antibody during spray drying resulted in a stabilized antibody product and a in decrease rates of aggregation when trehalose was utilized (see page 355).

Furthermore, formation of tablets or pellets for animal feed are well known in the art. Freeman teaches generally speaking, the animal feed is prepared by combining the ingredients of the animal feed to form a mixture, and forming discrete plural particles of the animal feed from the mixture. Most preferably, the particles are formed by palletizing the mixture. Those skilled in the

art of palletizing will appreciate that various conditions may be employed during the palletizing process. Generally speaking, moisture levels in the pellet mill may range from about 5% to about 12%, with a product temperature ranging from about 120.degree F. to about 250.degree. F. (see col. 4, lines 13-25). Pelleting allows for controlling amount of feed to different size animals by altering the size of the pellet.

Therefore, it would have been obvious to one of ordinary skill in the art to use trehalose with anti-PLA.sub.2 antibody because trehalose confers thermostability to dried formulations. It would have been further obvious to form pellets for feeding different size animals using conventional methods as taught in Freeman. Furthermore, during pelleting trehalose would confer thermostability to the animal feed mixture taught by Cook et al.

Response to Arguments

Applicants argue that the primary reference does not teach the use of a saccharide or specifically the use of trehalose. Applicants state that the secondary reference of Draber et al. does not remedy the primary reference since "Draber does not teach that the saccharide is necessary to preserve the antigen-binding activity of the antibody, nor does Draber teach nor suggest that the saccharide will preserve the antigen binding activity of an egg antibody upon exposure to an antigen binding activity destroying temperature of at least 70°C." For Andya, Applicants argue the reference does not teach that one can produce a feed containing heat stabilized egg antibody by mixing an eg with, an egg yolk containing an egg antibody and at least one saccharide. For Freeman, Applicants state that the reference "is not directed to producing feed containing heat stabilized egg antibodies." Finally, Applicants argue that a similar rejection was made in the office action dated September 26, 2007 but was withdrawn and "[t]he argument used to overcome the previous rejection is

incorporated herein and Applicants further that discussion to vigorously argue that Freeman, as described the preceding paragraph, does not cure the deficiencies of the combined teachings of Cook, Draber and Andya.

Applicants arguments have been fully considered but have not been found persuasive.

First with respect to withdrawal of the previous "almost identical rejection," the rejection was withdrawn in light of the amendments made to the claims on March 26 2008. The rejection was not withdrawn based on Applicants arguments. This was evident when the "almost identical rejection" was made subsequently with the addition of Freeman et al. to support a rejection corresponding to amended claims.

With respect to arguments regarding the rejection, Applicants argue that each reference individually does not teach the all of the limitations of the claims. It is acknowledged that the references individually do not teach all of the limitation. Had each reference taught all of the limitations of the claim, each reference would constitute prior art under 102 rather than 103. The reference combined provide a proper *prima facie* case under 103.

The primary reference teaches preparation of use of anti-phospholipids A2 antibodies to enhance growth or improve animal feed. The secondary reference provide motivation to use saccharide and motivation to form of tablets or pellets for animal feed, thereby exposing the fed to temperatures greater than 70°C. The motivation for the use of trehalose is that it confers thermostability to dried formulations (see Draber and Andya). Note that Andya teaches the use of trehalose in spray drying techniques to prevent aggregation. Applicants argue that none of the references teach the use of the saccharide for preserving the antigen binding activity of the antibody. However, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. ***It is not necessary that the prior***

art suggest the combination to achieve the same advantage or result discovered by applicant. See MPEP 2144. Here, the prior art provides motivation to use trehalose, namely trehalose provides effective stabilization during freeze-drying of IgM and such preparations can be stored at elevated temperatures and anti-IgE monoclonal antibody during spray drying resulted in a stabilized antibody product and a in decrease rates of aggregation when trehalose was utilized. The prior art also provide motivation to conduct all of the active method steps. The presence of trehalose would necessarily result the activity of stability as claimed.

Since the prior art provides motivation for using trehalose in formulations containing antibodies and motivation to form tablets and pellets, the rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach

the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/
Primary Examiner, Art Unit 1654